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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,160	11/09/2001	Everett Lee Rosey	DAVI110.001AUS	7229

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,160

Applicant(s)

ROSEY ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,25-30 and 34-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-21,25-29 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 38-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1645

### **DETAILED ACTION**

1. Applicant's amendment filed on 3/11/2004 is acknowledged.

#### **Status of Claims**

2. Claims 30 and 38 have been amended.

Claims 22-24 and 31-33 have been canceled

Claims 30 and 38-50 are currently under examination.

Applicant states that claims 30 and 38-50 remain in the present application. However, claims 1-21, 25-29 and 34-37 that are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions are also present in the application, said election made with traverse on 8/29/03.

Therefore, claims 1-21, 25-29, 30, 34-37 and 38-50 are pending in the application.

#### ***Objection to Drawings withdrawn***

3. The examiner acknowledges the new drawings under 37 C.F.R. 1.84 or 1.152 in response to previous office action and the drawings are placed in the application. Therefore, the objection to the drawings is withdrawn.

#### ***Specification – Informalities withdrawn***

4. In view of amendment to the specification, specification informalities are withdrawn.

#### ***Claim Rejection - 35 U.S. C. 112, first paragraph moot***

5. In view of cancellation of claims 22-24, the rejection under 35 U.S.C. 112, first paragraph is moot.

Art Unit: 1645

***Claim Rejections - 35 U.S. C. 112, first paragraph withdrawn***

6. In view of amendment to the claim 30, the written description and scope of enablement rejections under 35 U.S.C. 112, first paragraphs are withdrawn.

***Claim Rejections - 35 USC 112, second paragraph moot***

7. In view of cancellation of claims 22-24, 31-33, the rejection under 35 U.S.C. 112, second paragraph is moot

***Claim Rejection - 35 U.S. C. 112, first paragraph maintained***

8. The rejection of claims 30 and 38-50 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained as set forth in the previous office action.

The specification lacks complete information how to make the plasmid pGTE # 2 flhB (Accession number obtained at Netherlands, NMOO/16477). The specification teaches general description of amplifying the amino acid coding gene and making an expression vector. However, it fails to teach that the specific *Lawsonia cellularis* nucleic acid sequence SEQ.ID.NO: 1 that has been cloned as an expression plasmid pGTE # 2 flhB. In the absence of such a disclosure, the deposit of the NMOO/16477, plasmid pGTE#2 flhB is required. It is not clear that the expression plasmid pGTE#2 flhB are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the expression plasmid pGTE#2 flhB of the invention, a suitable deposit for patent purposes, evidence of public availability of the expression plasmid pGTE # 2 flhB of the invention or evidence of the reproducibility without undue experimentation of the expression plasmid pGTE # 2 flhB is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of

Art Unit: 1645

the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit.

Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if the test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid pGTE # 2 flhB, described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's arguments filed on 3/11/04 have been fully considered but they are not deemed to be persuasive.

Art Unit: 1645

Applicant states that the deposit was made in compliance with 37CFR 1.806 and 37CFR 1.808 (a) concerning the term of deposit and permissible conditions on access once the patent is granted.

The examiner has noted that the deposit NMOO/16477 (specification, page 2, lines 1-3) was made in Australia. However, the date of the deposit has not been disclosed. If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid pGTE # 2 flhB, described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may

Art Unit: 1645

submit a copy of the contract with the depository for deposit and maintenance of each deposit.

In the absence of such information in the application, the rejection is maintained.

***New Rejections - 35 USC 112, second paragraph.***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 30 and 39-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is vague for the recitation of "an isolated nucleic molecule comprising SEQ.ID.NO: 1". The expression SEQ.ID.NO is generally used to identify a sequence. For the purpose of distinctly claiming the subject matter, it is proper to recite the claim as "an isolated polynucleotide comprising the nucleotide sequence SEQ.ID.NO: 1" Or "an isolated polynucleotide sequence as set forth in SEQ.ID.NO: 1".

Claim 38 is rejected as being vague for the recitation of " of pGTE # 2 flhB AGAL (Accession number NMOO/16477)." It is not clear what applicant mean by " of pGTE # 2 flhB - -? " Does applicant intend to mean A plasmid pGTE # 2 flhB AGAL Accession number NMOO/16477?

***New Claim Objections***

11. Claims 40- 42 and 45-50 are objected as they depend from cancelled claims 31-33. Correction is required.

***Remarks***

12. Claims 30, 38-50 are rejected.

***Conclusion***

13. This application contains claims 1-21, 25-29 and 34-37 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.




Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

5/05/04

  
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